Mar Cor Purification

WRO 300

Operator's Manual

MAR COR® PURIFICATION

A Cantel Medical Company

Important User Information

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Intended Use

MCP products are intended to be installed and used as described in this manual and other related MCP literature.

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Preface

This manual provides the information needed to operate the WRO 300 water purification unit.

Valid program version	4.x

Other Manuals for WRO 300

The list below shows all manuals related to this Operator's Manual.

Service Manual	WRO 300 / WRO 300 H, 3027437
Installation Guide	WRO 300 / WRO 300 H, 3027502

Definitions of Expressions in the Manual

WARNING
Is used to alert the user/operator **not to take** a certain action, which if taken, can cause a potential hazard and result in a serious adverse reaction, injury or death. A warning may also be used to alert the user **to take** a certain action to avoid the potential hazard as above.

CAUTION
Is used to alert the user **to take** a certain action to protect against a potential hazard which, if ignored, could have an adverse effect on the patient or the device. A caution may also be used to alert the user **not to take** a certain action to avoid the potential hazard as above.

NOTE
A reminder to the user on normal treatment activity and on what is a suitable action in a particular situation.

Safety Considerations

WARNING
Unauthorized installation, modifications, alterations or repair of the WRO 300 may result in malfunctioning or have other serious consequences for the safe operation of the equipment.

WARNING
Dialysis machines that are supplied with water from the WRO 300 water purification unit must comply with IEC 60601-2-16.

CAUTION

- WRO 300 may be operated only by persons who have studied the instructions in this manual and the manual for the dialysis monitor. If the system does not perform as described in these manuals, it should not be used until the condition is rectified.
- The operator should pay attention to alarms and follow the instructions, warnings, cautions and notes in the manual.
- The WRO unit is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- The WRO 300 will perform as designed only if it is used and maintained in accordance with MCP written instructions. Any warranties made by MCP with respect to the WRO 300 are voided if the equipment is not used in accordance with the written instructions provided. MCP will not accept responsibility for any damage or injury resulting from improper use or maintenance or unauthorized repair.
- The use of mobile telephones or communication equipment in the vicinity of the WRO 300 could adversely influence the performance of the machine. See specification.
- WRO 300 needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Operator's and Service manual.
- US Federal law restricts this device to sale by or on the order of a physician.

NOTE

- During transportation and storage the equipment must be kept in its original packing. If transportation or storage time is more than 15 weeks the environmental data relating to the operation must be followed.
- For the qualified technician the WRO 300 / 300 H Service Manual is available. The Service Manual provides all of the necessary information for the safe and required maintenance of the machine.
- The WRO unit is intended for continuous operation.

List of Symbols

~	Alternating current
⏚	Protective earth (ground)
⚠	Warning, consult accompanying documents
○	Off (power, disconnection from the mains)
|	On (power, connection to the mains)

	Type B, applied part
	Handle with care
	This way up
	Keep dry
	Separate collection for electrical and electronic equipment
	Input /Output
	Year of manufacturing
IPX1	The WRO 300 is protected against dripping water
CB	Recycling symbol -General
	Reject water connection
	Feed water inlet connection
	Loop connections (Product water outlet and return)
	ME equipment and ME systems that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labeled with this symbol.

Certification Marks

The CSA(C-US) mark indicates that the WRO 300 water purification unit conforms to the requirements related to safety of medical devices for the US and Canada. The C and the US adjacent to the CSA mark indicates that the WRO 300 water purification unit has been evaluated to the applicable ANSI/UL and CSA standards for use in the US and Canada.

IPR - Intellectual Property Rights

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- DIALOX® is a trademark registered in several countries, including Sweden, United Kingdom and Japan by their respective owners.
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- MINNCLEAN® is a trademark of Minntech registered in several countries including the United States.
- STERICHECK® is a trademark registered in several countries including the United States and Japan by their respective owners.
- ULTRASIL® is a trademark of Ecolab registered in several countries including Australia and Canada.

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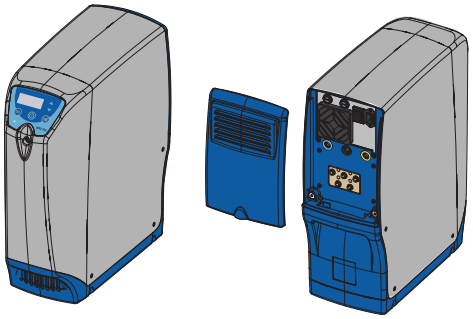
1 Introduction

1.1 Intended use

The MCP WRO 300 Water Purification Unit is intended to be used as a dialysis accessory to produce water by reverse osmosis for one hemodialysis equipment.

The WRO 300 can be connected to hemodialysis equipment used both in hospitals and in home environments with appropriate pre and post treatment units as a part of a water treatment system designed to meet regulations or standards for water for dialysis, for example current AAMI and Federal (U.S.) standards.

CAUTION
The water produced by WRO 300 should be analysed at installation and on a regular basis to verify that it conforms to applicable regulations or standards for water for dialysis.



1.2 General

The WRO 300 has been designed to fulfil the special requirements within a dialysis setting. This device has the following features:

- Simple user interface
- Chemical disinfection and cleaning modes
- Auto flush function during Standby periods to minimize stagnant water.

This manual for WRO 300 includes instructions for operating, monitoring, cleaning, disinfecting and troubleshooting this device from an operator's perspective. For installation instructions refer to the separate *Installation Guide*.

1.3 Alarm types

1.3.1 Notification

Next time the WRO goes to Standby the buzzer sounds, flashes, and the message displays.

Buzzer Sound	Description
Notification	_ _ _ _ _

1.3.2 Info

The WRO continues in the current mode. The message text will be displayed.

1.3.3 Alarm

The WRO continues in the current mode. The buzzer sounds, flashes and the message text displays.

Buzzer Sound	Description
Alarm	_ _ _ _ _

1.3.4 Stop

The WRO stops. The buzzer sounds, flashes and the message text displays.

Buzzer Sound	Description
Stop	_ _ _ _ _

1.4 Conductivity Monitoring

The conductivity monitoring system in the WRO 300 has three limits, allowing for individual adaptation of alarm settings to local preferences and regulations. The three limits are described in the sections below. All three limits are set at the factory.

> *NOTE*
> If the notification, alarm and stop limits are set to the same value the priority of the action are in the order of stop, alarm and notification.

1.4.1 Conductivity Notification (set at 20µS/cm)

Indicates that the product water conductivity is above normal reading. It will be issued when the WRO 300 enters Standby mode if the notification limit has been exceeded for more than 30 consecutive seconds during the previous run period. It may be caused by several reasons

such as incipient fouling, degradation of the RO membrane or change in the feed water quality.

> *NOTE*
> If the feed water conductivity is known to vary significantly, the conductivity notification limit should be inactivated by setting it at the same value as the conductivity alarm, see below.

1.4.2 Conductivity Alarm (set at 30µS/cm)

The clinic's predefined maximum product water conductivity for water for dialysis has been exceeded for more than 30 consecutive seconds. An audible and visual alarm will be issued. The WRO 300 will, however, continue in operation to allow for finishing the dialysis treatment.

The buzzer can be muted indefinitely by pressing , ▲ or ▼, however the button remains lit to indicate that the alarm persists.

1.4.3 Conductivity Stop (set at 60µS/cm)

The clinic's predefined maximum permissible product water conductivity has been exceeded for more than 30 consecutive seconds. An audible and visual alarm will be issued and WRO 300 will stop. The alarm can be acknowledged by pressing , ▲ or ▼. The WRO 300 can be restarted, but the alarm will reappear and the WRO 300 will stop after 30 seconds if the conductivity remains over the limit.

1.4.4 Setting of Conductivity Limits

- If the intention is to have an early warning of a change in the product water conductivity, set the notification limit at a value between the normal product water reading and the set alarm limit.
- If the intention is to stop operation in case of a conductivity alarm, set alarm and stop limits to the same value.
- If, in case of a conductivity alarm, the intention is to allow for continued dialysis in order to finish the ongoing dialysis treatment, set the alarm limit at the desired limit. The stop limit at which the WRO 300 will stop then has to be set at a higher value.

To adjust the limits, refer to the *Service Manual*.

1.4.5 Low Rejection Rate Notification

The rejection rate is the reduction percentage of the conductivity of the water in a reverse osmosis system. It depends on a number of factors such as conductivity, pH and temperature of the feed water and may vary significantly from one location to the other. It should therefore not be considered as an absolute measure of the quality of the water but rather as an indicator that can help to detect changes in performance of the WRO 300 which may be caused by incipient fouling or degradation of the RO membrane.

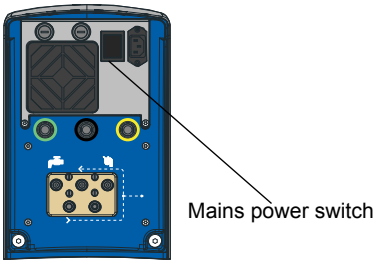
The low rejection rate notification default setting of 90% is relevant for most inlet water supplies. It may, however, need to be adjusted at

installation to a lower value by a qualified technician to fit local conditions, especially in cases of low feed water conductivity (<100 µS/cm). The limit should be set at least 5% lower than the initial value recorded at installation.

The low rejection rate notification will be displayed when the WRO 300 enters Standby if the set limit has been exceeded for more than 5 consecutive minutes during the previous run period.

1.5 Mains Power Switch

The mains power switch is only used in service situations to turn off the power. The mains power switch is located on the rear side behind a detachable cover.



1.6 Operator's Panel

1.6.1 Description of Buttons

Buttons	Description
⏻	Press to start operation (RUN).
	Press to stop operation (STANDBY).
Dis	Press to enter **SELECT** (only in Standby mode)
	Press to start the selected procedure (**SELECT** or **CHEM SELECT**).
	Press during the chemical intake procedure to pause.
	Press during dwell period to initiate rinse.
🔇	Press to silence audible alarms.
	Press to unlock the display and enter the alarm list.

Buttons	Description
	Used to scroll and view data in the display.
	Press any of the arrow buttons to unlock the display and enter the alarm list.
	Pressing both arrow buttons simultaneously will lock current information in the display. Press any arrow buttons to release the locking function.

1.6.2 Description of indications

Indications			Description
	Green	**General**	Indicates that the WRO 300 is energized.
	Green	**Steady light**	RUN mode, auto flush or manual flush in progress.
		Slow flash	The auto flush function is activated (only in standby mode).
		Fast flash	Insufficient feed water supply (only in RUN mode).
Dis	**Yellow**	**Steady light**	Chemical disinfection or cleaning is in progress.
		Medium flash	The disinfection wand connector is inserted into the chemical intake.
			During selection of procedure in **SELECT** or **CHEM SELECT.**
			The chemical intake phase is paused.
			Forced rinse is required (**404 RINSE REQUIRED**).
	Red	**Medium flash**	Unconfirmed notification, info, alarm or stop conditions are present.
		Steady light	Notification, info, alarm or stop condition has been confirmed.

1.6.3 Definition of Flash Indications

Flash indication	Time	
	On	**Off**
Slow flash	0.4 sec	2.0 sec
Medium flash	0.4 sec	0.4 sec
Fast flash	0.2 sec	0.2 sec

1.6.4 Reminders

Reoccurring notifications can be preset to remind the user to take certain actions, for example exchange cartridge in the pre-filter. When the reminder time expires the notification message will be displayed. Further information of setting the Reminders, refer to the *Service Manual*.

> *NOTE*
>
> After the reminder time has expired the notification message will only appear once!

1.6.5 Operational data

If any alarm (stop, alarm, info or notification) has been issued, the alarm list will appear first and can be scrolled and viewed by using the ▲ or ▼. Refer to the *Troubleshooting on page 37*.

By using ▲ or ▼ the operational data can be scrolled and viewed in the display.

Operational data		Unit
PRODUCT WATER		X µS/cm
FEED WATER		X µS/cm
REJECTION RATE		X%
PRODUCT WATER FLOW [1]		X ml/min
PRODUCT WATER TEMP		X °C
CHEM,	DAYS SINCE LAST [2]	X
ACID CLEAN,		X
ALKALINE CLEAN,		X
PROGRAM VERSION		X.y
TOTAL RUN TIME		X hr
DATE		yyyy-mm-dd
TIME		hh:mm:ss
INTERNAL SERVICE		Not applicable

1. A flow meter kit has to be installed
2. Visible depending on settings

Main view will reappear automatically after 15 seconds. It is also possible to return to the main view, by using either ▲ or ▼ to scroll through the alarm list and the operational data until the main view is displayed.

2 Operation

WARNING
This device does not remove chlorine and chloramines. If these substances are present in the feed water, carbon filtration is required to remove these substances. Severe patient injury may otherwise occur. A test for total chlorine of the pretreated water must be performed prior to initiating dialysis treatment. The level of total chlorine must be below 0.1 mg/l (ppm).

2.1 Start

Press ⏻ until light goes on.

RUN
X µS/cm

2.2 Stop

Press ⏻ until light goes out and the WRO 300 goes into standby mode.

STANDBY

NOTE
If power failure occurs during operation mode the procedure continues in the same phase as when the power failure occurred when the WRO 300 starts up again.

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3 Regular Maintenance

NOTE
The procedure below assume factory settings of the protocol.

3.1 Chemical Disinfection

The required chemical disinfection frequency to achieve the desired microbiological requirements for the product water depends on several factors, such as:

- The quality of the feed water.
- Local regulations regarding the microbiological quality of dialysis water, etc.
- Local preferences, for example regarding the use of chemicals.

No general rules can be given that cover all situations. The disinfection schedule should instead be based upon microbiological testing performed by the clinic. A maximum period between disinfections should then be established to ensure acceptable bacteriological quality of the product water according to the clinic standards.

As a guideline, MCP recommends a minimum frequency of weekly chemical disinfection to ensure consistent microbiological quality of the product water.

The use of an ultrafilter on the dialysis machine will remove possible contaminants originating from the product water and may therefore be used as a method to extend the time between chemical disinfection of the WRO 300.

If the WRO 300 will not be used for an extended period of time, weekly chemical disinfection will help maintain the microbiological quality of the product water.

For certain peracetic acid disinfectants, the manufacturer recommends that the WRO 300 be cleaned with an acid cleaning agent in accordance with the cleaning instructions prior to chemical disinfection. Refer to the section, *Cleaning on page 23*.

3.1.1 Approved Chemical Disinfectants

- MINNCARE® Cold Sterilant

  Required amount: 50 ml of concentrated disinfectant

CAUTION
Disinfectants may be toxic. Refer to the manufacturer Instructions.

CAUTION
A test for residual disinfectant after rinse must be performed before the initiation of the next dialysis session. The residual concentration of the disinfectant in the fluid must be below levels specified by the clinic or by national standards. It is essential to use an appropriate test method, either with proven sensitivity for the disinfectant or recommended by the manufacturer of the disinfectant.

3.1.2 Test Kit Example

- Minncare Residual Test Strips, MCP order number 185-40-004 (preferred).
- STERICHEK® Residual Peroxide, MCP order number WT811905 (alternate).

3.1.3 Chemical Disinfection Procedure

Chemical disinfection of the WRO, including product water loop.

CAUTION
The chemical container must be located below the chemical intake.

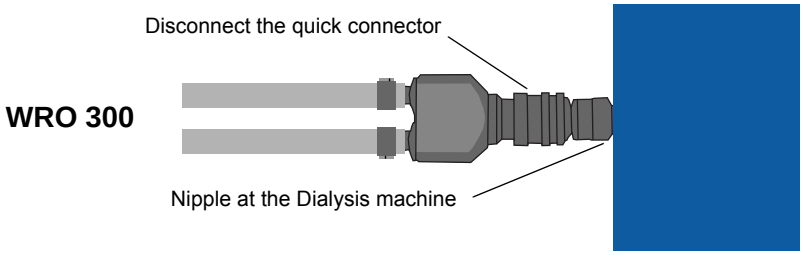
CAUTION
When requested by the WRO unit, remove the disinfection wand from the chemical intake. Failure to remove the disinfection wand can cause siphoning of the chemical solution from the bottle resulting in the tank overflowing chemical solution through the back of the machine.

NOTE
If power failure occurs during chemical disinfection **`404 RINSE REQUIRED`** is displayed when the WRO 300 restarts (also **`401 REMOVE WAND`** is displayed during the intake phase). Press Dis until light goes on, to initiate rinse.

Step 1 The WRO must be in Standby mode.

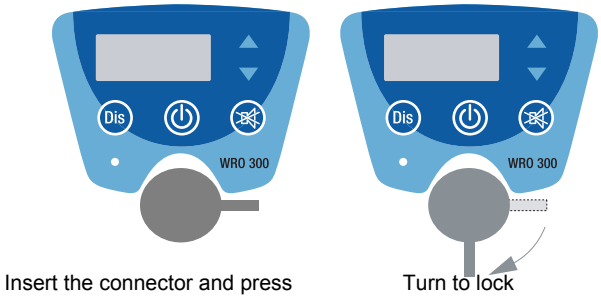
Step 2 Disconnect the WRO 300 from the dialysis machine with the quick connector on the product water loop — the connector can be left in place. Comply with the caution message below.

CAUTION
If the WRO 300 is not disconnected from the dialysis machine during the chemical disinfection procedure, the test for residuals after the chemical disinfection procedure must be performed on the dialysis machine according to the *Operator's Manual* of this device.



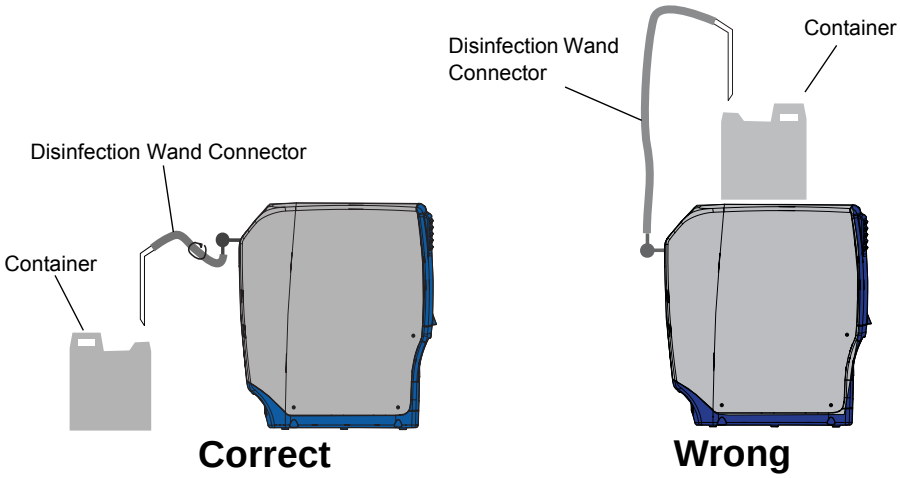
Step 3 Place a tag on the WRO 300, stating that chemical disinfection is in progress and what type of disinfectant is being used.

Step 4 Insert the wand connector into the chemical intake port of the WRO 300 (see the illustration below), press firmly and turn the connector downwards to lock. Check that the connector is securely in place.



Step 5 **CHEM SELECT** is shown in the display and Dis flashes.

Step 6 Insert the open end of the disinfection wand into a container with sufficient amount of disinfectant (refer to the *Approved Chemical Disinfectants on page 17*). Check that the open end of the intake wand is below the solution level and that the clamp is open. The container must be below the level of the chemical intake port to prevent siphoning chemical into the unit.



Step 7 From **CHEM SELECT**, press ▼ to enter the list of available Cleaning and chemical disinfection programs.

Step 8 Select preferred chemical disinfection program by using the arrow buttons.

```
MINNCARE
                ↕
```

Step 9 Initiate the disinfectant intake by pressing Dis until light goes on.

```
CHEM INTAKE
X µS/cm
```

> *NOTE*
> The display shows present phase of the chemical disinfection procedure.

> *NOTE*
> The container can be empty before the intake phase is finished.

> *CAUTION*
> The chemical disinfection has to be restarted if alarm **406 INSUFFICIENT INTAKE** has appeared.

The table below explains how to pause, interrupt or restart the procedure.

	Action
Pause of chemical intake phase	Press Dis until light flashes. To continue the intake press Dis again until light goes on.
Interrupt chemical disinfection procedure	Disconnect the wand connector and press Dis until light goes on, to initiate rinse.
Restart of intake phase	Remove the wand connector and insert it again **CHEM INTAKE RESTART** appears on the display and Dis flashes. Then press Dis until light goes on.

Step 10 **401 REMOVE WAND** is displayed and the buzzer sounds and is flashing, press .

Step 11 Keep the wand in the container and disconnect the wand by turning the connector a quarter of a turn and gently pull it out. Let the disinfectant liquid from the line and wand flow back into the container. Then clamp the line. Also check that correct amount of disinfectant has been consumed.

> *CAUTION*
> When requested by the WRO unit, remove the disinfection wand from the chemical intake. Failure to remove the disinfection wand can cause siphoning of the chemical solution from the bottle resulting in the tank overflowing chemical solution through the back of the machine.

Step 12 Remove the disinfection wand from the container and flush with water.

Step 13 The chemical disinfection procedure will now continue automatically with **DWELL PERIOD** followed by **RINSE**. The remaining time to complete the chemical disinfection procedure is also displayed.

> *NOTE*
> The conductivity value is checked during the final five minutes of the rinse phase. If the value is above the conductivity notification limit (refer to the section *Conductivity Monitoring on page 10*) when the preset rinse time is finished it is prolonged 30 minutes. If the value decreases below the conductivity notification limit the prolonged rinse finishes.
> If the level still is above the conductivity notification limit when the prolonged rinse is finished the alarm **403 HIGH CONDUCTIVITY RINSE** appears.

Step 14 When the chemical disinfection program is complete, the display will show **PERFORM RESIDUAL TEST**. The indication Dis will remain lighted and the ⏻ will flash.

3.1.4 Residual Test After Chemical Disinfection

> *CAUTION*
> If the WRO 300 has been connected to the dialysis machine during the chemical disinfection procedure, the test for residuals after the chemical disinfection procedure must be performed on the dialysis machine according to the *Operator's Manual* of the dialysis machine.

Step 1 Press ⏻ until light goes on, to start WRO 300.
Indication ⏻ will light and Dis will flash.

Step 2 Collect a water sample either from the product water line or from the dialysis machine according to the caution above.

Step 3 Test for disinfectant residuals with Minncare® Residual Peroxide test strips or other approved test strips or methods.

Step 4 Confirm by pressing Dis until light goes out. Indication remains on.

```
RUN
X µS/cm
```

Step 5 Remove any tag indicating storage with disinfectant.

If residuals are detected after starting the WRO 300 by pressing until the light goes on, repeat the residual test every five minutes until no residuals are detected.

3.1.5 Central Chem

The central chem disinfects the WRO and also sends disinfectant into the dialysis machine. For more detailed information on how to perform central chem together with Gambro® dialysis machines, please contact Technical Service.

CAUTION
If the produced disinfection solution is fed into a device other than Gambro® dialysis machines, it is the user's responsibility to ensure that the connected device is compatible with peracetic acid disinfectants and to establish the procedure for the WRO in combination with the connected device.

CAUTION
As the disinfection solution produced by the WRO will enter any device connected to the quick connector on the product water loop, residual test after disinfection must be performed on the connected device in accordance with the *Operator's Manual* for the connected device.

Follow the instructions in the *Chemical Disinfection Procedure on page 18* by starting at Step 3 and continuing to Step 13.

In Step 8 select the preferred central chem protocol in the **CHEM SELECT** menu.

```
CENTR_CH_PHX
```

> *NOTE*
> During the intake phase of the central chem program, the product water loop will not be pressurized until the correct conductivity has been obtained, which will take a few minutes.

3.2 Cleaning

3.2.1 Acid Cleaning

Acid cleaning should be performed when:

- Rejection rate has decreased by more than 5 percent from initial value.
- Sufficient output flow is not obtained.
- As preventive measure when a softener is not used.
- As a method to remove transitional metals from the RO membrane prior to chemical disinfection.

Dissolve 100 ml of citric acid in 200 ml of product water from the WRO 300. This will result in a 2 percent solution in the WRO 300 or use MINNCLEAN® AC according to manufacture's instruction.

Refer to *Cleaning Procedure on page 23*.

> *NOTE*
> Other acid membrane cleaner may be used as an alternative cleaner for the WRO 300. Follow manufacturer's guidelines to prepare the cleaning solution.

3.2.2 Alkaline Cleaning

Alkaline cleaning should be performed when:

- Product performance is affected and cleaning with acid does not improve performance.
- Organic fouling is suspected.

Use MINNCLEAN® TF according to manufacture's instruction.

Refer to *Cleaning Procedure* below.

3.2.3 Cleaning Procedure

Step 1 Press ⏻ until the display shows **RUN**. Wait until the product water conductivity stabilizes and record the value. Press ⏻ until light goes out to stop the WRO.

Step 2 Follow the chemical disinfection procedure, but instead select **ACID CLEAN,** or **ALKALINE CLEAN** in the **CHEM SELECT** menu. Refer to *Chemical Disinfection Procedure on page 18*.

> *NOTE*
> The container can be empty before the intake phase is finished.

3.2.4 Test for Residuals

Step 1 Press ⏻ until light goes on to start the WRO 300. Indication ⏻ lights and Dis flashes.

Step 2 Collect a water sample from the product water line.

Step 3 The absence of cleaning chemical in the product water is confirmed if the pH is within 1.0 pH unit of the feed water value (checked with a suitable method) and if the conductivity of the product water corresponds to the previously recorded value.

Step 4 Confirm by pressing Dis until the light goes out. Indication ⏻ remains lighted.

3.3 Long Term Storage

If the WRO 300 is to be taken out of operation for shorter periods of time chemical disinfection can be used to maintain the microbiological condition. This should be performed on a weekly basis or according to the schedule based on a microbiological testing, refer to *Chemical Disinfection on page 17*.

3.3.1 Preservation

If chemical disinfection (according to *Long Term Storage*) is not possible to perform when the WRO 300 is taken out of operation for an extended period of time (for example if electrical and water connections are disconnected) a chemical preservation has to be done.

3.3.1.1 Preservation Agent

Use MEMSTOR and dissolve 100 ml in two liters of potable tap water. Warm water (35 to 40 °C) speeds up dissolution.

3.3.1.2 Preservation Procedure

Step 1 Follow the chemical disinfection procedure (refer to *Chemical Disinfection on page 17*) Step 2 through Step 12, but instead select **MEMSTOR** in the **CHEM SELECT** menu.

> *CAUTION*
> If the conductivity limit is not achieved, alarm **406 INSUFFICIENT INTAKE** will appear and the Preservation procedure has to be restarted.

Step 2 After Step 12: the display will show **404 RINSE REQUIRED** and the buzzer will sounds and the indications Dis and flash. Press , ▲ or ▼ to acknowledge the alarm — the alarm list unlocks.

Step 3 Turn off the WRO 300 using the mains power switch behind the detachable cover.

3.3.2 Rinse After Preservation

Step 1 Turn on the WRO 300 using the mains power switch behind the detachable cover.

Step 2 The indicators Dis and flash and the display shows **404 RINSE REQUIRED**.

Step 3 Press Dis until light goes on to initiate rinse.

```
RINSE
hh:mm
```

Step 4 When the rinse program is complete, the display will show **PERFORM RESIDUAL TEST**. The indication Dis remains lighted and the ⏻ flashes.

3.3.3 Check for Complete Rinse-out

The required rinse program in the WRO has been designed and validated to ensure complete rinse-out of the preservation.

Step 1 Press ⏻ until light goes on to start the WRO— indicator ⏻ lights and Dis flashes.

Step 2 Let the WRO run in normal operation for at least 5 minutes. Then press ▲ or ▼ to show the conductivity value in the display (within 15 seconds the display returns to **PERFORM RESIDUAL TEST**). Check and verify that the product water conductivity remains stable and constant.

Step 3 Confirm by pressing Dis until light goes out. Indication ⏻ remains lighted.

Step 4 The WRO is now ready to use.

3.4 Flush

3.4.1 Manual Flush

This mode provides a short flush of the WRO at elevated flow rate (5 minutes preset).

Step 1 Press Dis until **SELECT** appears.

Step 2 Scroll with ▼ to select **MANUAL FLUSH**.

Step 3 Press Dis to initiate manual flush (**MANUAL FLUSH** shows and ⏻ lights).

3.4.2 Auto Flush

During standby auto flush is regularly performed to exchange water in the WRO, if it is enabled in preset. At specified intervals the water circulates in the WRO and some water goes to drain.

3.5 Exterior Cleaning

Wipe the outside of the WRO 300 with a cloth moistened with ethanol (70 percent) or isopropanol (60 percent).

> *NOTE*
> Do not use iodine-based or tenside-containing disinfectants as these may crack or discolor the plastic materials.

4 Technical Data

4.1 Performance and Specification

		Values
Product water	Output flow	Min. 1.1 l/min • at +10 °C feed water temperature • at 0.15 MPa (22 psi) pressure in the product water loop
	Product water loop	Maximum 20 meters (2 x 10 m)
	Product water pressure	0.12 to 0.6 MPa (17 to 87 PSI) during RUN mode (depending of the consumption from product water loop)
	Quality	Depends on feed water quality. If potable water is used, the following rejection rates will be obtained: Total dissolved salts: >96% (based on conductivity); at +10 °C feed water temperature Bacteria and endotoxins: >99%

		Values
Water supply	Input	Min. 3.0 l/min required
	Feed Water Pressure	During operation — there is an inlet flow of water into the WRO unit. 0.15 to 0.3 MPa (22 to 45 PSI)
		Maximum design pressure: 0.8 MPa (115 PSI)
		If the feed water pressure exceeds 0.3 MPa (45 PSI), a flow regulator, order number WTW522001001, should be installed.
	Feed Water Temperature	+5 to +30 °C
	Feed Water Quality	Potable water should be used.
		Particle filtration shall be used (<5 μm)
		Carbon filtration shall be used if water is chlorinated, see limits below.
		Membrane life expectancy might be reduced if the unit is operated outside of the following limits. For example, additional maintenance such as cleaning to remove scale from hard water buildup may be required if the hardness level is exceeded.
	Hardness	<1 °dH (20 ppm as $CaCO_3$) 1 grain/gallon
	Iron	<0.1 mg/l
	Manganese	<0.1 mg/l
	Turbidity	<1 JTU
	Total dissolved salts (TDS)	<1500 mg/l
	Fouling index (silt density index)	<5
	Chlorine (total)	<0.1 mg/l
Drain	Drain output flow during RUN mode	1.2 ±0.1 l/min
	Height difference between the drain hose outlet and the WRO 300 drain outlet.	Maximum 1.0 m
	Drain (length of hose)	Maximum 5 m
	Drain flow capacity	Minimum 3.0 l/min required

		Values	
Tank air vent	This outlet connects the tank to the atmosphere. This outlet must be connected with an air gap if plumbed to a drain. If a hose is connected to the Tank air vent, the hose shall have a constant slope.		
	NOTE Air will move back and forth in this line because of the variation of the level in the tank.		
Chemical intake	The machine is designed to bring in disinfectant/cleaning agent through the chemical intake. The maximum suction height from chemical intake is 600 mm.		
Fluid connections	Designed for flexible, reinforced tubing 8 mm x 2.5 mm (5/16” I.D.) The product water loop is designed for flexible, reinforced tubing 5 mm x 3 mm		
Conductivity measurement (temperature compensated)	Product water conductivity	Operating range	1–500 µS/cm
		Accuracy	±10% or ±10 µS/cm whichever is greater
	Feed water conductivity	Operating range	10 - 2000 µS/cm
		Accuracy	±10% or ±10 µS/cm whichever is greater
Temperature measurement	Operating range	0 to105 ºC	
	Accuracy	±4 ºC	
Reverse osmosis module	Membrane material	Polyamide, thin film composite	
	Membrane configuration	Spiral wound	
	Membrane pH tolerance	2 to 11	
Power supply	Mains Voltage	100 to 240 VAC (line voltage range 85 to 264 VAC)	
	Frequency	50 or 60 Hz (line frequency range 45 to 65 Hz)	
	Power Consumption Max	WRO 300	570 W 100–240 VAC
	Appliance inlet	According to IEC 60320; C14	
	Cable	Cable with protective earth Conductor length max. 3.5 m minimum 1 mm² (220–240 VAC) AWG 16 at 100 and 115 VAC	
	Mains plug	North America type—100 and 115 VAC, Hospital grade, earthed plug, type IEC 60 083; A5-15	
	Fuses	Not used	
	Earth Leakage Current	Max. 250 µA (220–240 VAC) Max. 145 µA (115 VAC) Max. 140 µA (100 VAC)	

		Values	
Connection of external equipment			
	External connector 8 pins REDEL, yellow.		
	Not used.		
	External connector 8 pins REDEL, black. USB		
	Logging interface	Max input voltage	±15 VDC
		High level min output voltage	5.0 VDC
		Low level max output voltage	5.0 VDC
		Max Current	±5 mA DC
	External connector 8 pins REDEL, green.		
	Not used.		
Sound	Sound power level	Less than 65 dBa during normal operation	

4.2 Chemical Disinfection and Cleaning

Disinfection	The following disinfectants may be administered via the chemical intake.
	• MINNCARE® Cold Sterilant • Other peracetic acid disinfectants, provided that they are approved by the manufacturer for disinfection of thin film composite reverse osmosis membranes made of modified polyamide. Follow the manufacturer instructions for Use for the specific disinfectant.
Cleaning agents	The following cleaning agents may be administered via the chemical intake: • Citric acid • Minnclean® AC • Minnclean® TF • Acetic Acid (5%) • Other cleaning agents may also be used, provided that they are approved by the manufacturer for cleaning of thin film composite reverse osmosis membranes made of modified polyamide. Follow the manufacturer's instructions for use for the specific cleaning agent.
Preservation	The following preservations may be administered via the chemical intake and feed water inlet: • MEMSTOR ® • MEMSTOR ® in combination with 9 % glycerol • Formalin
Exterior cleaning	• Ethanol (70%) • Isopropanol (60%).

4.3 Physical Data

Measurements	Values
Weight	29 kg (63.9 lb)
Height	563 mm (22.2 inch)
Depth	Max 520 mm (20.5 inch)
	Footprint 380 mm (15.0 inch)
Width	Max 205 mm (8.1 inch)
	Footprint 185 mm (7.3 inch)
Internal fluid volume	Approximately 3.5 litres excluding the product water loop

4.4 Materials Contacting Product Water

Type	Material
Polymers	PA (Polyamide) PEEK (Polyetheretherketone) PEI (Polyetherimide) PE (Polyethylene) PFA (Fluorocarbon) POM (Polyoxymethylene) PP (Polypropylene) PPS (Polyphenylensulphite) PVC (Polyvinylchloride) PVDF (Polyvinyliden fluorid)
Rubber	Q (Silicone)
Metals	Titanium Stainless steel
Others	Ceramic

4.5 Environmental data

		Value
Operation	Ambient Temperature range	+10 to +40 °C
	Relative Humidity range	30 to 85% RH
	Air Pressure range	700 to 1060 hPa
Transportation and storage	Ambient Temperature range	-10 to +40 °C
	Relative Humidity range	10 to 95% RH
	Air Pressure range	500 to 1060 hPa
	For transportation and storage below the freezing point, the WRO 300 must be filled with a preservation solution of 2% MEMSTOR, at least 9% glycerol and the remaining parts RO-water.	
	During transportation and storage the equipment must be kept in its original packing. If transportation or storage time is more than 15 weeks, the environmental data relating to the operation must be followed.	
	If condensation occurs when moving the equipment between locations with different temperatures and high relative humidity (for example. outdoor and indoor locations), the inside of the equipment must be allowed to dry before switching on the equipment.	

4.6 Electromagnetic Environment

		Value	
The WRO 300 is intended for use in the electromagnetic environment specified below. The customer or the user of the WRO 300 should assure that it is used in such an environment.			
Emissions test	**Compliance**	**Electromagnetic environment — guidance**	
RF emissions CISPR 11	Group1	The WRO 300 uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The WRO 300 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 61000-3-2	Class A (Not applicable for 115 V version)		
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies (Not applicable for 115 V version)		
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD)IEC 61000-4-2	±6 kV contact ±8 kV Air	±6 kV contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Surge IEC 61000-4-5	±1 kV for differential mode ±2 kV for common mode	1 kV for differential mode ± 2kV for common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T [1](>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

		Value	
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance[2]**
Conducted RFIEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the WRO 300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RFIEC 61000-4-3	3 V/m 80 MHz to 3.0 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 to 800 MHz[3] $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF mobile phones	-	30 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [4], should be less than the compliance level in each frequency range[5]. Interference may occur in the vicinity of equipment marked with the following symbol:

	Value		
Recommended separation distances between portable and mobile RF communications equipment and the WRO 300			
The WRO 300 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WRO 300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WRO 300 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d=\left[\frac{3.5}{3}\right]\sqrt{P}$	80 MHz to 800 MHz [6] $d=\left[\frac{3.5}{3}\right]\sqrt{P}$	800 MHz to 3 GHz $d=\left[\frac{7}{3}\right]\sqrt{P}$
0,01	0.11	0.11	0.23
0,1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23
Rated maximum output power of mobile phone	-	-	$d=\left[\frac{7}{30}\right]\sqrt{P}$
2W GSM/3G	-	-	0.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

1. NOTE: UT is the AC mains voltage prior to application of the test level.
2. NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
3. NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.
4. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the WRO 300 is used exceeds the applicable RF compliance level above, the WRO 300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the WRO 300.

5. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
6. NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

4.7 Safety

The machine complies with the following standards:
IEC 60601-1 General requirements for safety, Class I, type B, and IPX1.
IEC 60601-1-2 Electromagnetic compatibility.

5 Troubleshooting

In alarm situations the message text will appear in the display. Only the latest message will be visible in the display. By using the , or the display will be unlocked and the alarm list can be scrolled.

The main view will reappear after a time period.

5.1 Alarms and Notifications

5.1.1 General

No.	Alarm and Notifications	Definition	
101	CONDUCTIVITY SENSOR FAILURE	WRO 300	Buzzer sounds with alarm sound, flashes, message text displays.
		Reason	The initial conductivity system check failed.
		Action	1 Press , or to silence buzzer. 2 Check that the product water conductivity is within normal range. If so, continue as normal but notify technical personnel.
102	HIGH LEVEL SENSOR FAILURE	WRO 300	WRO 300 stops, buzzer sounds with Stop sound, flashes, message text displays.
		Reason	Failure of high level sensor in tank.
		Action	1 Press , or to silence buzzer. 2 Notify technical personnel.
103	: N INTERNAL ERROR [1]	WRO 300	WRO 300 stops, buzzer sounds with stop sound, flashes, message text displays.
		Reason	Control unit failure.
		Action	1 Press , or to silence buzzer. 2 Restart unit, or notify technical personnel.
104	INVALID WATER LEVEL	WRO 300	WRO 300 stops, buzzer sounds with alarm sound, flashes, message text displays.
		Reason	Failure of level sensors in tank.
		Action	1 Press , or to silence buzzer. 2 Check that no water has flooded from the Tank air vent. 3 The WRO 300 can be restarted bypressing . 4 Otherwise notify technical personnel.

1. The number (N) shown before the alarm text identifies which specific kind of alarm that has occurred. Reference list for those number refer to *Service Manual.*

5.1.2 Operation

No.	Alarm and notifications	Definition	
201	CONDUCTIVITY NOTIFICATION	WRO 300	When entering Standby mode, buzzer sounds with notification sound, flashes, message text displays.
		Reason	The conductivity value has exceeded the notification limit for more than 30 consecutive seconds during previous run period.
		Action	1 Press , or to silence buzzer. 2 Perform cleaning according to local procedures. 3 If problem persists notify technical personnel.
202	CONDUCTIVITY ALARM	WRO 300	Buzzer sounds with alarm sound, flashes, message text displays.
		Reason	The conductivity value has exceeded the alarm limit for more than 30 consecutive seconds.
		Action	Before treatment 1 Press , or to silence buzzer. 2 Note the conductivity value. 3 Continue treatment. After treatment: 1 Inform responsible medical staff according to local procedures. 2 Notify technical personnel for further action.
203	CONDUCTIVITY STOP	WRO 300	WRO 300 stops, buzzer sounds with alarm sound, flashes, message text displays.
		Reason	The conductivity value has exceeded the stop limit for more than 30 consecutive seconds.
		Action	1 Press , or to silence buzzer. 2 Inform responsible medical staff according to local procedures. 3 The WRO 300 can be restarted by pressing . It will stop again if the problem persist. 4 If problem persists discontinue dialysis. 5 Notify technical personnel.
204	INSUFFICIENT WATER SUPPLY	WRO 300	WRO 300 stops, flashes fast, message text displays.
		Reason	Lack of feed water.
		Action	1 Check the feed water supply. 2 Notify technical personnel.

No.	Alarm and notifications	Definition	
205	LOW REJECTION RATE	WRO 300	When entering standby mode, buzzer sounds with notification sound, flashes, adn message text displays.
		Reason	Decreased membrane performance.
		Action	1 Press , or to silence buzzer. 2 Perform cleaning according to local procedures. 3 If problem persists notify technical personnel.
206	LOW PRODUCT FLOW	WRO 300	When entering standby mode, buzzer sounds with notification sound, flashes, and message text displays.
		Reason	The product water flow is below the preset notification limit which indicates that the performance of the membrane is reduced. For WRO 300 an optional flow measuring kit has to be installed — otherwise the preset notification limit has to be disabled.
		Action	1 Press , or to silence buzzer. 2 Perform cleaning according to local procedures. 3 Notify technical personnel.

5.1.3 Chemical, Cleaning, Rinse and Preservation

No.	Alarm and Notifications	Definition	
401	REMOVE WAND	WRO 300	Buzzer sounds with alarm sound, flashes, message text displays.
		Reason	Wand connector not removed after completion of chemical intake.
		Action	1 Press , or to silence buzzer. 2 Remove wand from disinfectant intake port.
402	INSUFFICIENT WATER SUPPLY	WRO 300	WRO 300 stops, buzzer sounds with alarm sound, flashes, message text displays.
		Reason	Lack of feed water.
		Action	1 Press , or to silence buzzer. 2 Check the feed water supply. 3 Check for leakage. 4 Restart by pressing Dis . 5 Notify technical personnel if problem persists.

No.	Alarm and Notifications	Definition	
403	HIGH CONDUCTIVITY RINSE	WRO 300	Buzzer sounds with alarm sound, flashes, message text displays.
		Reason	Conductivity value is above conductivity notification limit after a prolonged rinse.
		Action	1 Press , or to silence buzzer. 2 Perform an extra rinse by pressing Dis until rinse starts. 3 If problem persists notify technical personnel.
404	RINSE REQUIRED	WRO 300	Buzzer sounds with alarm sound, and Dis flashes, message text displays.
		Reason	The WRO is filled with chemicals.
		Action	1 Press , or to silence buzzer. 2 Perform rinse by pressing Dis until rinse starts.
405	INCORRECT WATER LEVEL	WRO 300	WRO 300 stops, buzzer sounds with alarm sound, and Dis flashes, message text displays.
		Reason	Water level in tank is lower than expected.
		Action	1 Press , or to silence buzzer. 2 Check that the dialysis machine is turned off. 3 Press Dis to restart. 4 If the problem persists notify technical personnel.
406	INSUFFICIENT INTAKE	WRO 300	Buzzer sounds with alarm sound, and Dis flashes, message text displays.
		Reason	The product water conductivity is below the minimum intake conductivity limit.
		Action	1 Press , or to silence buzzer. 2 If the disinfection wand is inserted and Dis is pressed a second intake phase is started. 3 If the disinfection wand is not inserted and Dis is pressed the WRO continues to dwell period.

No.	Alarm and Notifications	Definition	
408	INSERT WAND	WRO 300	WRO 300 stops, buzzer sounds with alarm sound, flashes, message text displays.
		Reason	A central chemical disinfection has been initiated via the remote control and the disinfection wand is not inserted.
		Action	1 Press , or to silence buzzer. 2 Insert the disinfection wand to continue the central chemical disinfection procedure.

5.2 Boot loader

This alarm indicate that the software is corrupt.

No.	Alarm and notifications	Definition	
	LOAD APPLICATION FAILED	WRO 300	**LOAD APPLICATION FAILED** is shown on the display.
		Reason	Software malfunction.
		Action	Notify technical personnel.

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6 Check List

Serial no:_____

Check conductivity with separate instrument

		Feed water		Product water		Reject		
Date	**Hours in operation**	**Conductivity µS/cm**	**Temp °C**	**Conductivity µS/cm**	**Flow l/min**	**Flow l/min**	**Rejection rate %**	**Remarks**

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